REMARKS

Reconsideration of this application as amended, is requested.

Claims 1, 3, 4, 6 and 8 remain in the application and under consideration. Claims 2, 5 and 7 are canceled. Claims 9-17 remain in the application, but have been withdrawn based on the response to the restriction requirement. Claim 1 has been amended to define the invention more clearly and to incorporate limitations that previously were in claim 7.

Claims 1, 3 and 6 were rejected under 35 U.S.C. 103(a) as being obvious over Kasai considered in view of Newby et al., Wermund and Knowles.

As noted above, claim 1 has been amended to incorporate the limitations of claim 7. Accordingly, the obviousness rejection based on Kasai in view of Newby et al., Wermund and Knowles is believed to have been overcome by this amendment.

Claim 7 had been rejected under 35 USC 103(a) as being obvious over Kasai, Newby et al., Wermund, Knowles and Miller. It is believed that the Examiner would apply this hypothetical combination of five references to amended claim 1. Hence, this combination of five references is considered below in the context of amended claim 1.

The invention defined by amended claim 1 is directed to a method for manufacturing closures for evacuated fluid collection tubes. The closures of the subject invention desirably should meet several objectives. First, the closures should maintain an evacuated condition within the tube for an acceptably long period of time. Thus, the closure should be substantially impermeable to liquid and gas. Second, the closure should be pierceable by a needle so that fluid, such as blood, can be collected into the evacuated tube. Third, the closure should provide a desirable degree of sealing after the fluid has

been deposited into the tube so that the collected fluid does not interact with the surroundings between the time the fluid is collected and the time the fluid is analyzed. Fourth, the closure also should resist "push-off" forces that are exerted as fluid begins flowing into the evacuated tube. In this regard, forces exerted by fluid exiting a needle and entering the evacuated tube tend to push the tube and the needle in opposite directions and can cause the needle to separate from the tube and the closure. This separation can expose health care workers to infectious material that may be carried by the blood and result in a loss of blood for the patent. Fifth, the closure should be safely separable from the tube so that the collected fluid can be accessed for analysis. The sudden movement and pressure changes that result upon removal of the closure can cause fluid in the tube to spray. Hence, the closure desirably should minimize the risk of exposing health care workers to such spraying of fluid. All of the above-identified objectives also should be achieved with a manufacturing process that can be completed efficiently and cost effectively.

Amended claim 1 is directed to a method for manufacturing closures that meets all of the above-described objectives in a cost effective and efficient manner. The method comprises a first step of providing a sheet of laminated sealing material. The sheet has a first outer layer formed from a thermoplastic material, an intermediate layer of metallic foil adjacent the first outer layer and a second outer layer. The metallic foil of the sealing material provides a very good barrier for maintaining the evacuated condition of the tube for an extended tie. The first and second outer layers of the sealing material are well suited to attaching the sealing material to other components of the closure and to the evacuated fluid collection tube. The method of amended claim 1 then includes moving the

sheet of sealing material to a molding apparatus and molding substantially cylindrical elastomeric stoppers onto substantially planar sections of the second outer layer of the sheet at spaced apart locations on the sheet. The substantially cylindrical elastomeric stoppers are molded to define outside diameters that are approximately equal to or slightly greater than inside diameters of the fluid collection tubes. The in situ molding of the elastomeric stoppers achieves several manufacturing efficiencies. In particular, it is unnecessary to obtain separate inventories of elastomeric stoppers and circular discs of sealing materials and then accurately securing stoppers onto the circular discs of sealing material. Second, the in situ molding of the elastomeric stoppers onto the sheet of laminated sealing material simplifies the use of adhesives in connection with the manufacture of evacuated fluid collection tubes. In this regard, other manufacturing processes would require selection of materials and adhesives so that the sealing material can be adhered to the top of the rigid fluid collection tube and so that the same surface of the sealing material can be adhered to an elastomeric stopper. The in situ molding of the elastomeric stoppers onto the sealing material also simplifies both the selection of material and the attachment. Third, the in situ molding of the elastomeric stoppers onto the sheet of sealing material simplifies the handling, storage and transportation of the closures.

The method of amended claim 1 then includes cutting the sheet into circular shapes surrounding portions of each of the elastomeric stoppers on the sheet. The circular shapes define diameters greater than the diameters defined by the stoppers and greater than the inside diameter of the fluid collection tube. Thus, an annular area of the second outer layer of the sealing material projects out from the stopper. The method then includes providing outer caps. Each outer cap has a cylindrical skirt with top and bottom

ends. An annular shoulder extends in from the top end of the skirt and an aperture is formed centrally in the annular shoulder. The annular shoulder has a bottom surface facing towards the bottom end of the skirt. The method then includes adhering the first outer layer of the seal to the bottom surface of the annular shoulder such that the stopper is disposed within and spaced from the skirt.

Closures produced by the claimed method can be telescoped to the open top of the fluid collection tube so that the elastomeric stoppers sealingly engage the inner circumferential surface of the fluid collection tube. Additionally, the skirt of the outer cap telescopes over and around the outer circumferential surface of the fluid collection tube adjacent the top. Still further, the second outer layer of the sealing material between the elastomeric stopper and the skirt of the outer cap can be sealed to the top edge of the fluid collection tube.

A tube produced according to this method can be accessed by passing a needle through the aperture defined in the annular shoulder of the outer cap. The needle then pierces the sealing material and passes through the elastomeric stopper. The elastomeric material of the stopper exerts a gripping force on the needle to prevent push-off in response to forces generated by the flow of fluid into the tube. The needle can be withdrawn after collection of a selected amount of fluid. The elastomeric material of the stopper then reseals substantially to protect the collected fluid. The skirt that surrounds the top part of the fluid collection tube provides protection against splashing if the closure must be removed from the tube for accessing the collected fluid.

The Examiner relies upon the FIG. 5 embodiment of Kasai as the primary reference in the complex combination of five references set forth in the office action. FIG.

5 of Kasai shows a blood collecting tube 41 with a sealing member 42 that consists of a gas barrier 44 with a layer of adhesive 43 applied to the bottom surface. A rubber sealing element 45 then is attached to the central portion of the lower surface of the adhesive film 43. Thus, Kasai must deal with the above-referenced problems of selecting an adhesive that is compatible with the gas barrier film 44, the material of the tube 41 and the rubber of the sealing element 45. Kasai specifically does not want the rubber sealing member 45 to contact the inner periphery of the tube 41.

The Newby et al. reference is assigned to the assignee of the subject invention, and hence the applicant herein is familiar with the teaching of Newby et al. The Newby et al. reference teaches a circular sheet of laminated sealing material that can be applied across the top edge of a tube. A layer of resealable material is applied to the exterior surface of the laminated sealing material and then is secured to an interior portion of a cap by hot melt adhesive. Thus, although both Kasai and Newby et al. relate to the general environment of the subject invention, neither suggests in situ molding of an elastomeric stopper onto an inwardly facing surface of a sealing material with the stopper being dimensioned for sealing engagement with the interior of the collection tube for which the closures are being manufactured.

Wermund relates to a closure that can be snapped into and out of engagement with a food container. The closure includes a base with a generally tapered hollow tubular side wall formed to have a relatively rigid shape so that the side wall of the base of the lid can be snapped into and out of engagement with structure on the food container and so that several food containers can be stacked. A thin flexible membrane extends across the top wall of the plastic base of the lid and is formed from a material that

preferably can accommodate printing on the outer surface of the food container lid. The thin membrane is placed in the mold cavity that is used to injection mold the relatively rigid plastic base of the lid.

Knowles relates to a method for molding a lid for a container, such as a food container. The lid is constructed to have a rigid rim with a transparent plastic center. The Knowles method passes the transparent film into a molding apparatus. Knowles then injects a plastic material into an annular cavity surrounding a part of the transparent film and simultaneously deforms the plastic film into an annular channel shape. The composite of the transparent plastic film and the rigid channel-shaped annular ring then are die cut to form the cap. The resulting cap has a transparent center window and an opaque channel-shaped rim that can be snapped into engagement with the top of a food container. The channel-shaped rim necessarily includes both the transparent film and the opaque plastic that provides the structural integrity.

Miller also is assigned to the assignee of the subject invention and relates to a closure where an elastomeric material extends across the top edge of a tube. A cap with a cylindrical skirt and an annular shoulder is mounted over the closure.

Nothing in the five references relied upon by the Examiner suggests their hypothetical combination. It is submitted, with respect that the combination would be made only with the benefit of hindsight gleaned from the disclosure of the subject application. Independent of this disclosure, there is nothing that would motivate the skilled artisan to pick and choose elements of these very different processes and combine those different elements into a method that suggests the method of amended claim 1. Three of the references relied upon in the office action are drawn from the evacuated tube art.

However, none of these references suggest molding an elastomeric stopper onto a sheet of laminated sealing material prior to cutting the laminated sealing material into a specified shape. Additionally, none of these references suggest molding the elastomeric stopper to have cylindrical dimensions appropriate for sealing the evacuated fluid collection tube for which the closures are being manufactured. Two of these three references that relate to evacuated tubes have a rigid cap. However, none of the reference with a cap have an elastomeric stopper positioned inwardly from the skirt of the cap below both the sheet of sealing material and the shoulder of the cap.

The two references that are drawn from fields other than the evacuated fluid collection tube art relate to molding a rigid plastic material with a plastic film to define a cap that can be snapped into engagement with a food container. Wermund disposes a membrane in a mold cavity and then molds a rigid plastic to a portion of the membrane. Knowles molds an annular plastic channel to a transparent film while simultaneously deforming the plastic film into the annular channel shape.

Since none of the references teach molding elastomeric stoppers onto planar sections of a laminated sealing material, it is not seen how the hypothetical combination of these references possibly could suggest these features. None of the references suggest molding the elastomeric stoppers to have diameters substantially equal to or slightly greater than the inside diameters of the fluid collection tubes. Hence, the hypothetical combination of the references could not teach or suggest this aspect of the invention. None of the references suggest cutting the sheet of sealing material into circular shape surrounding the stoppers that have been molded onto the sheets of sealing material. Hence, the combination of these references cannot teach this aspect of the invention.

None of the references teach or suggest adhering a first outer layer of the seal to the bottom surface of an annular shoulder so that the stopper is disposed within and spaced from the skirt of the outer cap.

Dependent claims 3, 4, 6 and 8 were rejected under 35 USC 103(a) as being obvious over the previously cited references considered further in view of other references. The additional references do not overcome the deficiencies of the five references considered above.

In view of the preceding amendments and remarks, it is submitted that the claims remaining in the application are directed to patentable subject matter, and allowance is solicited. The Examiner is urged to contact applicant's attorney at the number below to expedite the prosecution of this application.

Respectfully submitted,

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